CLAIM AMENDMENTS

1. (currently amended)A solid ~~pharmaceutical~~ composition comprising an active ingredient selected among tacrolimus and analogues thereof, wherein less than 20% w/w of the active ingredient is released within 0.5 hours, when subjected to an in vitro dissolution test using USP Paddle method and using 0.1 N HCI as dissolution medium.

2. (currently amended) The solid ~~pharmaceutical~~ composition according to claim 1, wherein less than 20% w/w of the active ingredient is released within 3 hours.

3. (currently amended) The solid ~~pharmaceutical~~ composition according to claim 1, wherein less than 10% w/w of the active ingredient is released within 3 hours.

4. (currently amended) The solid ~~pharmaceutical~~ composition according to claim 1, wherein at least 50 % w/w of the active ingredient is released within 4 hours when subjected to an in vitro dissolution test using USP Paddle method and using 0. 1 N HCI as dissolution medium during the first 2 hours and then using a dissolution medium having a pH of 6.8.

5. (currently amended) The solid ~~pharmaceutical~~ composition according to claim 1, wherein at least 50 % w/w of the active ingredient is released within 2.5 hours when subjected to an in vitro dissolution test using USP Paddle method and using 0. 1 N HCI as dissolution medium during the first 2 hours and then using a dissolution medium having a pH of 6.8.

~~8.~~ 6. (currently amended) A solid ~~pharmaceutical~~ composition according to claim 1, wherein less than 50 w/w% of the active pharmaceutical ingredient is released within 8 hours, preferably within 15 hours, when subjected to an in vitro dissolution test using USP Paddle method and an aqueous dissolution medium adjusted to pH 4.5 with 0.005% hydroxypropylcellulose.

~~9~~7. (currently amended) The composition according to claim ~~8~~6, wherein less than 40 w/w% of the active pharmaceutical ingredient is released within 8 hours, preferably within 15 hours.

~~10~~8. (currently amended) The composition according to claim 1, which is designed to substantially avoid CYP3A4 metabolism in the gastrointestinal tract upon oral administration.

~~11~~9. (currently amended) The composition according to claim ~~10~~8, wherein the composition is coated with an enteric coating.

~~12~~10. (currently amended) The composition according to claim 1 comprising a solid dispersion or solid solution of active ingredient in a hydrophilic or water-miscible vehicle and one or more modifying release agents.

~~13~~11. (currently amended) The composition according to claim 1, wherein the active ingredient is dispersed or dissolved in a hydrophobic vehicle.

~~14~~12. (currently amended) The composition according to claim ~~13~~11, wherein the hydrophobic vehicle is an oil, an oily material, a wax or a fatty acid derivative.

~~15~~13. (currently amended) The composition according to claim ~~14~~12, wherein the hydrophobic vehicle is selected from the group consisting of straight chain saturated hydrocarbons, sorbitan esters, paraffins; fats and oils such as cacao butter, beef tallow, lard, polyether glycol esters; higher fatty acid such as stearic acid, myristic acid, palmitic acid, higher alcohols such as cetanol, stearyl alcohol, low melting point waxes such as glyceryl monostearate, glyceryl monooleate, hydrogenated tallow, myristyl alcohol, stearyl alcohol, substituted and/or unsubstituted monoglycerides, substituted and/or unsubstituted diglycerides, substituted and/or unsubstituted triglycerides, yellow beeswax, white beeswax, carnauba wax, castor wax, japan wax, acetate monoglycerides ; NVP polymers, PVP polymers, acrylic polymers, and mixtures thereof.

~~16~~14. (currently amended) The composition according to claim ~~15~~13, wherein the hydrophobic vehicle is glyceryl monostearate (GMS).

~~17~~15. (currently amended) The composition according to claim ~~12~~10, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyethylene glycols, polyoxyethylene oxides, poloxamers, polyoxyethylene stearates, poly-epsilon caprolactone, polyglycolized glycerides such as Gelucire®, and mixtures thereof.

~~18~~16. (currently amended) The composition according to claim ~~12~~10, wherein the hydrophilic or water-miscible vehicle is selected from the group consisting of polyvinylpyrrolidones, polyvinyl-polyvinylacetate copolymers (PVP-PVA), polyvinyl

alcohol (PVA), polymethacrylic polymers (Eudragit RS; Eudragit RL, Eudragit NE, Eudragit E), cellulose derivatives including hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, pectins, cyclodextrins, galactomannans, alginates, carragenates, xanthan gums and mixtures thereof.

~~19~~17. (currently amended) The composition according to claim ~~12~~10, wherein the vehicle is a polyethylene glycol (PEG).

~~20~~18. (currently amended) The composition according to claim ~~12~~10, wherein the polyethylene glycol has an average molecular weight of at least 1500.

~~21~~19. (currently amended) The composition according to claim ~~12~~10 comprising a mixture of two or more hydrophilic or water-miscible vehicles.

~~22~~20. (currently amended) The composition according to claim ~~12~~10, wherein the mixture comprises a polyethylene glycol and a poloxamer in a proportion of between 1: 3 and 10: 1, preferably between 1: 1 and 5: 1, more preferably between and 3: 2 4: 1, especially between 2: 1 and 3: 1, in particular about 7: 3.

~~23~~21. (currently amended) The composition according to claim ~~12~~10, wherein the poloxamer is poloxamer 188.

2422. (currently amended) The composition according to claim ~~12~~10, wherein the polyethylene glycol has an average molecular weight of about 6000 (PEG6000).

2523. (currently amended) The composition according to claim 1, which further comprises one or more modifying release agents selected from the group consisting of water-miscible polymers, water- insoluble polymers, oils and oily materials.

2624. (currently amended) The composition according to claim ~~25~~23, wherein the water-insoluble polymer is selected from the group consisting of ethyl cellulose, cellulose acetate, cellulose nitrate, and mixtures thereof.

2725. (currently amended) The composition according to claim ~~26~~24, wherein the oil or oily material is hydrophilic and selected from the group consisting of polyether glycols such as polypropylene glycols ; polyoxyethylenes ; polyoxypropylenes ; poloxamers ; polyglycolized glycerides such as Geluciree and mixtures thereof.

2826. (currently amended) The composition according to claim ~~27~~25, wherein Gelucire®; is selected among Gelucire® 50/13, Gelucire® 44/14, Gelucire® 50/10, Gelucire® 62/05 and mixtures thereof.

2927. (currently amended) The composition according to claim ~~25~~23, wherein the oil or oily material is hydrophobic and selected from the group consisting of straight chain saturated hydrocarbons, sorbitan esters, paraffins ; fats and oils such as cacao butter, beef tallow, lard, polyether glycol esters; higher fatty acid such as stearic acid, myristic acid, palmitic acid, higher alcohols such as cetanol, stearyl alcohol, low melting point waxes

such as glyceryl monostearate, glyceryl monooleate, hydrogenated tallow, myristyl alcohol, stearyl alcohol, substituted and/or unsubstituted monoglycerides, substituted and/or unsubstituted diglycerides, substituted and/or unsubstituted triglycerides, yellow beeswax, white beeswax, carnauba wax, castor wax, japan wax, acetate monoglycerides ; NVP polymers, PVP polymers, acrylic polymers, and mixtures thereof.

~~30~~28. (currently amended) The composition according to claim ~~25~~23, wherein the oil or oily hydrophobic material has a melting point of at least about 20°C.

~~31.~~29. (currently amended) The composition according to claim ~~25~~23, wherein the water-miscible polymer is a cellulose derivative selected from the group consisting of hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), methylcellulose, sodium carboxymethylcellulose, hydroxyethyl cellulose, poloxamers, polyoxyethylene stearates, poly-s-caprolactone, polyvinylpyrrolidone (PVP), polyvinylpyrrolidone-polyvinylacetate copolymer PVP-PVA, polymethacrylic polymers and polyvinyl alcohol (PVA), poly (ethylene oxide) (PEO) and mixtures thereof.

~~32~~30. (currently amended) The composition according to claim ~~31~~29, wherein the polymethacrylic polymers are selected among Eudragit® RS, Eudragit® RL, Eudragit® NE and Eudragit® E.

~~33~~31. (currently amended) The composition according to claim ~~1~~9, which is entero-coated using a water-miscible polymer having a pH-dependant solubility in water.

~~34~~32. (currently amended) The composition according to claim ~~33~~31, wherein the water-miscible polymer is selected from the group consisting of polyacrylamides ; phthalate derivatives such as acid phthalate of carbohydrates including amylose acetate phthalate, cellulose acetate phthalate, cellulose acetate terephtahalate, cellulose acetate isophthalate, other cellulose ester phthalates, cellulose ether phthalates, hydroxypropyl cellulose phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropyl ethylcellulose phthalate, hydroxypropyl methylcellulose phthalate (HMPCP), methylcellulose phthalate, methyl cellulose acetate phthalate, polyvinyl acetate phthalate, polyvinyl acetate hydrogen phthalate, sodium cellulose acetate phthalate, starch acid phthalate ; phthalate of other compounds including polyvinyl acetate phthalate (PVAP); other cellulose derivatives including hydroxypropyl methylcellulose acetate succinate (HPMCAS), carboxymethylcellulose, cellulose acetate trimellitate ; alginates ; carbomers; polyacrylic acid derivatives such as acrylic acid and acrylic ester copolymers, polymethacrylic acid and esters thereof, poly acrylic methacrylic acid copolymers, methacrylic acid copolymers (for example Eudragit® L and Eudragit® S); styrene-maleic acid dibutyl phthalate copolymer, styrene-maleic acid polyvinylacetate phthalate copolymer, styrene and maleic acid copolymers ; shellac, starch glycolate ; polacrylin ; vinyl acetate and crotonic acid copolymers and mixtures thereof.

~~35~~33. (currently amended) The composition according to claim 1, which further comprises one or more pharmaceutical acceptable excipients.

~~36~~34. (currently amended) The ~~pharmaceutical~~ composition according to claim ~~35~~33, wherein the pharmaceutically acceptable excipients are selected from the group consisting of fillers, diluents, disintegrants, binders and lubricants.

~~37~~35. (currently amended) The ~~pharmaceutical~~ composition according to claim ~~35~~ 33 in particulate form, for example in powder form.

~~38~~36. (currently amended) The ~~pharmaceutical~~ composition according to claim 35, wherein the particles have a geometric weight mean diameter dgw from about 10 um to about 2000 um, preferably from about 20 um to about 2000 um, especially from about 50 um to about 300 um.

~~39~~37. (currently amended) The ~~pharmaceutical~~ composition according to claim 35, wherein the particles have a geometric weight mean diameter dgw from about 50 um to about 300 um.

~~40~~38. (currently amended) A dosage form comprising the ~~pharmaceutical~~ composition according to claim 35, which is a solid oral dosage form.

~~41~~39. (currently amended) The dosage form according to claim ~~40~~38, which is a unit dosage form.

~~42~~40. (currently amended) The dosage form according to claim ~~40~~38, which further comprises a pharmaceutically acceptable additive selected from the group consisting of flavoring agents, coloring agents, taste-masking agents, pH-adjusting agents, buffering agents, preservatives, stabilizing agents, anti-oxidants, wetting agents, humidity-adjusting agents, surface-active agents, suspending agents and absorption enhancing agents.

~~43~~41. (currently amended) The dosage form according to claim ~~40~~38, wherein at least one pharmaceutically acceptable excipient is selected from the group consisting of silica acid or a derivative or salt thereof including silicates, silicon dioxide and polymers

thereof; magnesium aluminosilicate and/or magnesium aluminometasilicate, bentonite, kaolin, magnesium trisilicate, montmorillonite and/or saponite.

4442. (currently amended) The dosage form according to claim 4041, wherein at least one pharmaceutical acceptable excipient is a silica acid or a derivative or salt thereof.

4543. (currently amended) The dosage form according to claim 4041, wherein at least one pharmaceutically acceptable excipient is silicon dioxide or a polymer thereof.

4644. (currently amended) The dosage form according to claim 4543, wherein the silicon dioxide product has properties corresponding to Aeroperle 300, (available from Degussa, Frankfurt, Germany).

Claims 45-50 (canceled)

5351. (currently amended) A method for the preparation of the composition according to claim 1210, the method comprising the step of dissolving or dispersing tacrolimus or an analogue thereof in a hydrophilic vehicle to obtain a solid solution or dispersion at ambient temperature.